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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 29/00 — A3

(11) International Publication Number: WO 94/06502

(43) International Publication Date: 31 March 1994 (31.03.94)

(21) International Application Number: PCT/US93/08346

(22) International Filing Date: 3 September 1993 (03.09.93)

(30) Priority data:
07/949,095 22 September 1992 (22.09.92) US
07/975,376 13 November 1992 (13.11.92) US

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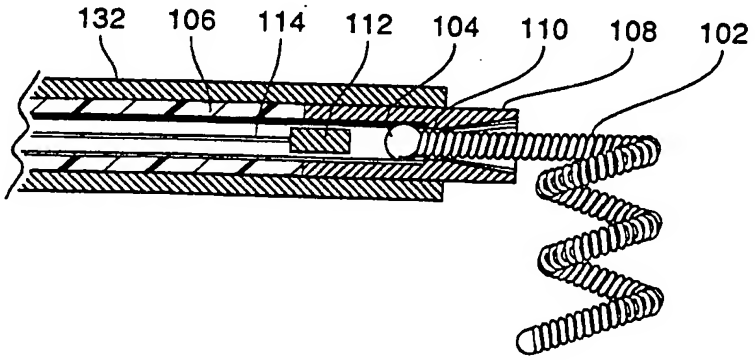
(81) Designated States: AU, CA, CZ, FI, HU, JP, KR, NO, NZ, SK, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:
28 April 1994 (28.04.94)

(54) Title: DETACHABLE EMBOLIC COIL ASSEMBLY



(57) Abstract

This invention is a surgical instrument and specifically is a device for delivering embolic coils to a selected site within the vasculature of the human body via use of a catheter. In particular, the device (100) involves an embolic coil (102) having a radially enlarged member (104) attached to one end, which coil is released by forcing the radially enlarged member axially through a distensible aperture (108) situated on the distal end of a pusher assembly (100). Alternatively, the embolic coils (208) may be mounted on a guide wire (206) and a pusher sheath (210) within the catheter sheath (202) used to push through the coils (208) through the end (204) of the catheter sheath (202). The catheter (202) has a constricted distal tip (204) or other means of frictionally controlling the release of embolic coils (208). Additionally (or alternatively), the guide wire tip (207) may engage the embolic coils (208) from their interior to allow precise placement of the coils (208).

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DETACHABLE EMBOLIC COIL ASSEMBLY

RELATED APPLICATIONS

This is a continuation-in-part of U.S. patent application Ser. No. 07/975,376, filed November 13, 1992, (Atty. Docket No. 29025-20045.00) entitled "Axially Detachable Embolic Coil Assembly" and of U.S. patent application Ser. No. 07/949,095, filed September 22, 1992, (Atty. Docket No. 29025-20047.00) entitled "Assembly for Placement of Embolic Coils Using Frictional Placement", the entirety of which are incorporated by reference.

FIELD OF THE INVENTION

This invention is a surgical instrument and specifically is a device for delivering embolic coils to a selected site within the vasculature of the human body via use of a catheter. In particular, the device involves an embolic coil having a radially enlarged member attached to one end, which coil is released by forcing the radially enlarged member axially through a distendible aperture situated on the distal end of a pusher assembly. Alternatively, the embolic coils may be mounted on a guidewire and a pusher sheath within the catheter lumen used to push through the coils through the end of the catheter lumen. The catheter has a constricted distal tip or other means of frictionally controlling the release of embolic coils. Additionally (or alternatively), the guidewire may engage the embolic coils from their interior to allow precise placement of the coils.

BACKGROUND OF THE INVENTION

The endovascular treatment of a variety of vascular maladies throughout the body is an increasingly more important form of therapy. Catheters have been used to place various treatment materials, devices, and drugs within arteries and veins in the human body. Examples of these devices and their use in such treatments are shown in U.S. Patent Application Nos. 07/806,898 ("Detachable Pusher-Vasoocclusive Coil Assembly with Threaded Coupling") and 07/806,912 ("Detachable Pusher-Vasoocclusive Coil Assembly with Interlocking Ball and Keyway Coupling"). These documents show methods and devices for delivery of coils or wires within the human body to sites such as aneurysms, to occlude those sites. Coils such as are discussed in those two documents (as well as in U.S. Patent No. 4,994,069), may be of a regular or helical configuration or may assume a random convoluted configuration at the site. The coils normally are made of a radiopaque, biocompatible metal such as platinum, gold, tungsten, or alloys of these and other metals. In treating an aneurysm it is common to place a number of coils within the aneurysm. The coils occlude the site by posing a physical barrier to blood flow and by promoting thrombus formation at the site.

Coils have typically been placed at the desired site within the vasculature using a catheter and a pusher. The site is first accessed by the catheter. In treating peripheral or neural conditions requiring occlusion, the sites are accessed with flexible, small diameter catheters such as those shown in U.S. Patent Nos. 4,739,768 and 4,813,934 may be used. The catheter may be guided to the site through the use of guidewires (see U.S. Patent No. 4,884,579) or by the use flow-directed means such as balloons placed at the distal end of the catheter. Use of guidewires involves the

placement of relatively long, torqueable proximal wire sections within the catheter attached to more flexible distal end wire sections designed to be advanced across sharp bends at vessel junctions. The guidewire is visible using x-ray and allows a catheter to be placed in vessels taking extremely tortuous paths, even when those vessel are surrounded by soft tissue such as the brain.

Once the chosen site has been reached, the catheter lumen is cleared by removing the guidewire (if a guidewire has been used), and the coil is placed into the proximal open end of the catheter and advanced through the catheter with a pusher. Pushers are wires having a distal end that is adapted to engage and push the coil through the catheter lumen as the pusher is advanced through the catheter. When the coil reaches the distal end of the catheter, it is discharged from the catheter by the pusher into the vascular site. This technique of discharging the coil from the distal end of the catheter has a number of undesirable limitations. First, because of the plunging action of the pusher and the coil, the positioning of the coil at the site cannot be controlled to a fine degree of accuracy. Second, once the coil has left the catheter, it is difficult to reposition or retrieve the coil if such is desired.

Several techniques have been developed to enable more accurate placement of coils within a vessel. In one technique (U.S. Patent No. 5,122,136, issued June 16, 1992) the coil is bonded via a metal-to-metal joint to the distal end of the pusher. The pusher and coil are made of dissimilar metals. The coil-carrying pusher is advanced through the catheter to the site and a low electrical current is passed through the pusher-coil assembly. The current causes the joint between the pusher and the coil to be severed via electrolysis. The pusher may then be retracted leaving the detached coil at

an exact position within the vessel. In addition to enabling more accurate coil placement, the electric current may facilitate thrombus formation at the coil site. The only perceived disadvantage of this method is that the electrolytic release of the coil requires a period of time so that rapid detachment of the coil from the pusher does not occur.

Another technique for detaching an embolic coil is shown in U.S. Patent Application 07/806,912. In that document, a coil having an enlarged portion is mated with a pusher having a keyway adapted to receive the enlarged portion of the coil in an interlocking relationship. The junction between the pusher and the coil is covered by a coaxial member. The coaxial member is movable by sliding the member axially. As the coaxial member is moved away from the junction where the coil's member engages the keyway of the pusher, the coil disengages and the pusher may be removed.

Another device for placement of coils is shown in U.S. Patent Application 07/806,898. This device includes a coil having a helical portion at one end and a pusher which is threaded to the inside of the helical coil by the use of a threaded section on the outside of the pusher. The device operates to discharge the coil by engaging the proximal end of the coil with a sleeve while the pusher is unthreaded. Once the pusher is free, the sleeve may be used to push the coil out into the treatment area.

Another method of placing an embolic coil is shown in U.S. Patent No. 5,108,407. This patent shows the use of a device in which embolic coils are separated from the distal end of a catheter by the use of heat-releasable adhesive bonds. The coil adheres to the therapeutic device via a mounting connection. Laser energy is transferred through a fiber optic cable which

terminates at the connector. The connector becomes warm and releases the adhesive bond between the connector and the coil.

U.S. Patent No. 3,334,629, to Cohn, suggests the use of a pusher having a socket to push an occlusive device within the inferior vena cava. However, the device's rounded end is not used to retain the occlusive device within the end of the inserter.

None of these disclosed devices suggest the devices disclosed here in which a distal constriction, on a catheter or on a pusher, is used to precisely place embolic coils (optionally having an enlarged member on their ends) within the vasculature.

SUMMARY OF THE INVENTION

This invention is a device for placing detachable coils at a site within the vasculature of the human body so to occlude that site using the coils. The device centers around the concept that embolic coils may be readily delivered to a site within the vasculature by ejecting them through a constricted section of a catheter or a pusher.

In one variation, the combination device includes a coil that carries an enlarged member (such as a ball or other rounded shape) at its proximal end; a pusher housing which has a distendible receiver, e.g., a socket, at its distal end having a throat or aperture which is smaller in diameter than the diameter of the member on the coil but which will distend to allow the ball to pass therethrough. This variation of the device also includes a plunger which is situated within the pusher housing and will press the coil's receiver through the distendible throat and thereby uncouple the coil from the pusher. This variation of the invention also

includes the apparatus used to refit the distal end of the pusher with additional coils.

Another variation of this invention includes:

(a) a catheter sheath preferably having a constricted tip at its distal end;

(b) a guidewire, optionally with a steerable tip at its distant or distal end, located within the catheter sheath, which guidewire is further optionally capable of internally engaging the embolic coils;

(c) at least one embolic coil on the guidewire proximal of the distal end of the guidewire;

(d) a pusher sheath fitting coaxially within the catheter sheath, the guidewire passing through it, and located proximally of the coils on that guidewire.

The pusher sheath will push one or more embolic coils out through the end of the catheter sheath, which end is preferably constricted or is otherwise capable of frictionally controlling the movement of those coils through the distal end of the catheter sheath. The pusher sheath also moves the embolic coils over the tip of the guidewire. When used, the constricted tip of the catheter controls the number of coils exiting the catheter with relative ease depending upon the axial movement of the pusher sheath. As an alternative, the one or more of the interior of the embolic coils may be sized so that a helical wire on the guidewire tip engages the inside of the embolic coils in a nut-and-bolt relationship so that the steerable tip may be screwed through the interior of the most distal embolic coil before it is released. Alternatively, an auger may be placed on the proximal end of the steerable tip to wind its way through the interior of the embolic coils if the size differential between the steerable tip and the embolic coil is sufficiently large.

Another portion of the invention is a method for occluding a selected site within a vessel comprising the steps of: (a) accessing the site with a distal end of a catheter; (b) advancing the assembly described above through the catheter with the assembly situated at the proximal end of the pusher housing's throat to a position out the end of the distal end of the catheter; (c) axially detaching the coil from the catheter; and (d) withdrawing the catheter (and pusher from) the vessel. An alternative to step (d) may include the step of reloading the catheter with one or more additional coils while leaving the catheter in place.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an enlarged, partial sectional view of one variation of the pusher-coil assembly showing the coil after uncoupling.

Figures 2 and 3 show variations of the tip of the socket on the pusher housing.

Figure 4 is an enlarged view showing the distal end of the pusher housing, the plunger, and the ball on the coil engaged.

Figure 5 is an enlarged view showing the distal end of the pusher housing, the plunger, and the ball on the coil not engaged.

Figures 6, 7, and 8 show the procedure for reloading the pusher housing with another embolic coil.

Figure 9 shows a schematic side view of a variation of the invention using a tube aperture on the distal end of the pusher.

Figures 10-12 are enlarged semi-cross-sectional views of another variation of the of the pusher embolic coil assembly invention showing the release of the coil from the distal end of the catheter.

In the drawings, the following convention is used: the proximal end is to the left and the distal end is to the right.

DESCRIPTION OF THE INVENTION

One variation of the pusher-coil assembly (100) is shown in Figure 1. The coil (102) is depicted to be helical in form, although it may be random or any other suitable form. The coil should be of a size sufficiently small that it may be advanced through a catheter that is appropriately sized for accessing the targeted vascular site. For instance, when accessing a brain aneurysm in a small vessel, an appropriately sized catheter is quite small and very flexible. The coil in such a situation must be small enough to fit through the catheter and out its distal end at the treatment site.

The coil is desirably made up of a radiopaque, physiologically compatible material. This material may be platinum, gold, tungsten, or alloys of these. A preferred material is a platinum or platinum/tungsten alloy. A number of polymers are also suitable as coil material either alone or in conjunction with metallic markers providing radiopacity. These materials are chosen so that the process of locating the coils within the vessel may be viewed using radiography. However, it is also contemplated that these coils may be made of various other biologically inert polymers or of carbon fiber.

The size of the coil and its constituent winding will depend upon the use to which the coil will be placed. For occluding peripheral or neural sites, the coils will typically be made of 0.05 to 0.15 mm diameter wire that is wound to have an inner diameter of 0.15 to 1.5 mm with a minimum pitch -- that is to say that the

pitch is equal to the diameter of the wire used in the coil. The length of the coil will normally be in the range of 0.5 to 60 cm, preferably 0.5 to 40 cm.

If desired, the coil may be formed in such a way that the coil is essentially linear as it passes through the catheter and yet assume a randomly oriented relaxed condition after it is released from the distal end of the catheter. A discussion of this variation may be found in U.S. Patent No. 4,994,069.

Attached to coil (102) is a radially enlarged member, or ball (104). Ball (104) is firmly attached to coil (102) and should not separate during the installation treatment nor thereafter. The remainder of assembly (100) is made up of a pusher housing (106) which is a sheath or tube extending from the proximal end of the assembly (100) to the distal end terminated by a distendible aperture, a socket (108). Socket (108) includes a necked-down portion, a throat (110), which throat has a distendible aperture with a diameter smaller than that of ball (104). The ball (104) is pushed through throat (110) of socket (108) by a plunger head (112). Plunger head (112) easily fits within the aperture of throat (110) so to push ball (104) with its attached coil (102) out into the target site. The socket may have a constant inner diameter instead of the varying diameter shown in Figure 1. Plunger head (112) is pushed via a pusher wire (114). Pusher wire (114) may, as is shown in Figure 1, have a larger diameter at the proximal end of the assembly than at the distal end of the assembly near plunger head (112). In other variations, the diameter of pusher wire (114) may be constant throughout. The pusher wire (114) is desirably actuated by a screw-driven apparatus (116) and (118) in which as a knob (118) is rotated, the pusher wire (114) is advanced

axially, distally down through the assembly (100) to push ball (104) out of the aperture (110) of socket (108).

The length of assembly (100) will be such as to be capable of being advanced entirely through the catheter to place coil (102) at the target site but yet with a sufficient portion of the proximal end of the assembly (100) protruding from the proximal end of the catheter to enable the plunger to be manipulated. For use in peripheral or neural surgeries, the pusher will normally about 100-200 cm in length, more normally 130-180 cm in length. The diameter of the pusher housing is usually in the range of 0.25 to about 0.90 mm.

Two variations of the socket are shown are shown in Figures 2 and 3. These variations are optional and are intended to lower the force needed to press ball (104) out through the throat of the socket aperture and yet hold the ball otherwise in a set position. In Figure 2, socket (120) incorporates a number of slots (122) which extend through the wall of the socket and terminate down near the resting place of the ball. This variation allows the ball to be firmly held inside of the socket throat (124) and yet be ejected easily using the plunger apparatus shown in Figure 1. Figure 3 similarly shows side cross-sectional views and end views of a socket which has grooves (128) cut from the distal end of the socket down into the aperture area (130). In each of Figures 2 and 3, the respective throat diameters (124) and (130) are each smaller than the diameter of the ball which is placed through them.

Assembly (100) is used to place one or more coils at the target site generally using the procedure as follows. As is shown in Figure 4, the coil (102) with its attached ball (104) are included into socket (108) with the ball pushed past socket throat (110). Catheter (132) is inserted and navigated through to the chosen

vessel site. The assembly (100) is then included into the catheter lumen to the site to be occluded.

As indicated previously, conventional catheter insertion and navigational techniques involving guidewires or flow-directed devices may be used to access the site with a catheter. Once the distal end of the catheter is positioned at the site, often by locating its distal end through the use of radiopaque materials of construction and radiography, the catheter is cleared. For instance, if a guidewire has been used to position the catheter, it is withdrawn from the catheter and then the assembly (100) is advanced through the catheter. The assembly (100) is advanced past the distal end of the catheter (132) so that the coil is free of the catheter and with the coil positioned precisely at the desired treatment site. As is shown in Figure 5, plunger wire (114) is advanced to press the ball (104) and its attendant coil (102) into the target site. The entire catheter may then be removed or the assembly (100) may be withdrawn from the catheter lumen to provide for installation of other coils. If additional coils are to be placed at the target site, the procedure is repeated. After the desired number of coils have been placed at the site, the catheter is withdrawn from the vessel.

Figures 6, 7, and 8 show a method for reloading the assembly (100). Figure 6 shows a coil introducer (150) which includes coil (102) and a ball (104). The coil introducer (150) is cylindrical and adapted to hold a coil (102) and a ball (104) in such a fashion as to allow entry of assembly (100) to one end and allow engagement of throat (110) over ball (104). As is shown in Figure 7, the plunger head (112) is positioned out of the way as the ball is pressed through throat (110) into the position shown there. After the introduction of the ball (104) is complete, assembly (100) is withdrawn from

coil introducer (150) as is shown in Figure 8, then placed in a catheter lumen and passed axially along to the target site as described above.

Figure 9 shows a variation of the invention in which the distendible aperture at the distal end (168) of the pusher is of a relatively constant inside diameter. Figure 9, the aperture is simply the end of a portion of tubing (170). The tubing (170) distal end (168) provides a friction fit with the coil (174) and with the coil end (172).

In this variation, a guide wire (176) having a tip marker (170) to allow observation of the position of the tip of the guide wire in relation to the coil (174), is used as is the pusher in the variations noted above. The guide wire (170) is used to push the coil (174) with coil end (172) axially through the tubing distal end (168). After such movement, the tubing distal end (168) returns to its original internal diameter.

A further variation of the inventive assembly is shown in Figures 10-12. The assembly, generally designated (200), is shown in Figure 10, and is made up of four principal parts:

(a) a catheter sheath (202) having a distal end (204) which is shown to be constricted but may be of other frictionally engaging shapes suitable for controlling the discharge of the coil through the catheter sheath distal tip;

(b) a guidewire (206) having a tip (207), which desirably is steerable;

(c) one or more coils (208) for placement at the treatment target site; and

(d) a pusher sheath (210) located coaxially and somewhat loosely within catheter sheath (202).

Coils (208) are shown in Figure 10 as uniform diameter helical coils in a straight configuration.

Obviously, the coils (208) may be of the type which, upon release from the catheter, either maintain the straight configuration or acquire some other form, e.g., a random configuration or as shown in U.S. Pat. No. 4.994,069. The coils (208) must be dimensioned so as to fit through the inner diameter of catheter sheath (202) as well as fit over the guidewire (206). Typically, the pusher sheath (202) is the sole motivator of the coils although, as noted below, a tip attached to the guidewire may assist in the placement of the coils. In any case, the movement of the coil from the distal end of the catheter must be accomplished with relative ease.

The coils (208) themselves may be of the same composition, configuration, and size as those discussed above.

Coils (208) are slipped onto guidewire (206). Guidewire (206) may have at its distal end a steerable segment (207). Steerable tip (207) is typically made up of a fine winding of wire wrapped about the distal portion of guidewire (206). The tip need not be of the steerable type, e.g., it may instead be of a short length of a coil winding or a mere deposit of a polymer or a metal, but of a size able to just engage the interior of the coil (208) in a frictional manner and allow meticulous control of the coil discharge by the pusher sheath (210). The pusher sheath (210) is placed proximally on the guidewire (206) within the catheter sheath (202). This system allows several coils (208) to be loaded on the proximal end of a guidewire before or during a procedure. The pusher sheath (210) can advance the coils towards the catheter tip while the guidewire remains within the catheter lumen. The guidewire may be reloaded with additional coils by removing the pusher sheath and the guidewire from the catheter lumen, placing additional coils placed on the guidewire, and re-

advancing the guidewire-coil-sheath subassembly into the catheter lumen.

The length of assembly (200) will be such that it is capable of being advanced entirely through the catheter to place one or more coils (208) at the target vascular site and yet having a sufficient portion of the proximal end of the assembly (200) protruding from the proximal end of the catheter so to allow manipulation of the pusher sheath (210). For use in peripheral or neural surgeries, the pusher will normally be about 100-200 cm in length, more normally 130-180 cm in length. The diameter of the pusher sheath (210) is usually in the range of 0.25 to about 1.50 mm, preferably 0.25 to 1 mm.

Figure 11 shows the assembly (200) after the distal end has reached the target site. The guidewire (206) may be retracted or, at the option of the operating physician, be allowed to remain out of the distal section of the assembly (200), and the pusher sheath is advanced to push one coil (208) through the constricted tip (204). The constricted tip (204) prevents additional coils from easily leaving through the catheter tip (204).

Figure 12 shows retraction of the guidewire (206) and a steerable tip (207) into the confines of the catheter sheath (202). Embolic coil (208) is free of the assembly (200).

Modifications of the device described above and methods of using it in keeping with this invention that are apparent to those having skill in this mechanical and surgical instrument design art and related fields are intended to be within the scope of the claims which follow.

I CLAIM AS MY INVENTION:

1. A detachable embolic coil comprising a coil having ends and an enlarged member fixedly attached to one of said ends.

2. The detachable coil of claim 1 where the enlarged member is a ball.

3. The detachable embolic coil of claim 1 where the coil material is selected from platinum, gold, tungsten, or alloys of these.

4. The detachable embolic coil of claim 1 where the coil material is a polymer.

5. The detachable embolic coil of claim 1 where the coil material is carbon fiber.

6. A pusher-coil assembly for use in occluding a selected site within a vessel comprising:

(a) a coil having an enlarged member fixedly attached to its proximal end;

(b) a pusher housing having a socket at its distal end, said socket having a throat aperture diameter smaller than the diameter of the enlarged member fixedly attached to the coil; and

(c) a plunger located within the pusher housing that is axially movable relative to the pusher housing and coil from a first position to a second position which pushes the coil and the enlarged member through the socket throat and thus uncouple the coil from the pusher-coil assembly.

7. The assembly of claim 6 where the enlarged member is a ball.

8. The assembly of claim 6 where the coil is helical, random, or straight.

9. The assembly of claim 6 where the distal socket end is slotted.

10. The assembly of claim 6 where the socket throat is grooved.

11. The assembly of claim 6 additionally comprising a plunger wire.

12. The assembly of claim 11 additionally comprising means for advancing the plunger wire and plunger head.

13. A method for occluding a selected site within a vessel comprising the steps of:

(a) accessing the site with a distal end of a catheter;

(b) advancing the assembly of claim 7 through the catheter with the ball attached to the coil located proximally of the throat in the socket to a position distally of the distal end of the catheter;

(c) extending the pusher head against the ball to detach the coil from the pusher-coil assembly; and

(d) withdrawing the catheter and assembly from the vessel.

14. A detachable pusher-coil assembly for use in occluding a selected site within a vessel comprising:

(a) a catheter sheath having proximal and distal ends and wherein the interior of distal end is adapted to frictionally engage but allow passage of embolic coils;

(b) a guidewire extending from the proximal to distal end of the catheter sheath and within the catheter sheath and having a tip suitable for frictionally engaging the interior of embolic coils;

(c) one or more embolic coils situated on said guidewire having a diameter sufficiently large to frictionally engage the interior of the catheter sheath's distal tip; and

(d) a pusher sheath situated within the inside diameter of the catheter sheath proximal to the coils and in which the guidewire passes therethrough,

whereby the pusher sheath may be moved axially towards the distal end of the catheter sheath and thereby push one or more coils through the distal end of the catheter sheath and off the distal end of the guidewire.

15. The assembly of claim 14 where the catheter housing distal end is constricted.

16. The assembly of claim 14 where the coils are helical coils.

17. The assembly of claim 16 where the coils are of a straight configuration.

18. The assembly of claim 16 where the coils are of a random configuration.

19. The assembly of claim 14 where the number of coils is more than one.

20. The assembly of claim 14 in which the guidewire tip is steerable.

21. The assembly of claim 20 in which the outer diameter of the steerable tip approximates the inner diameter of the one or more coils.

22. The assembly of claim 14 in which the embolic coils are of a radio opaque material.

23. The assembly of claim 22 in which the radio opaque material is selected from platinum, tungsten, gold or their alloys.

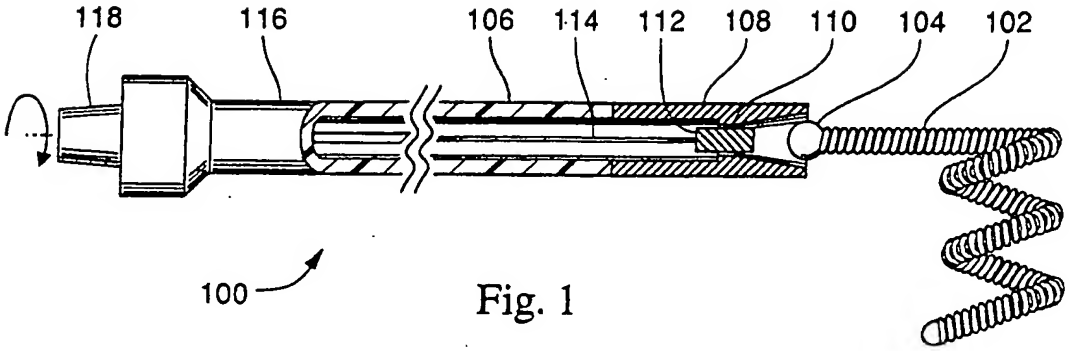

Fig. 1

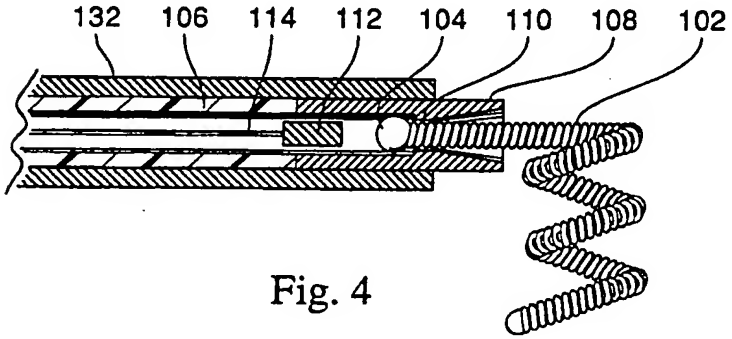

Fig. 4

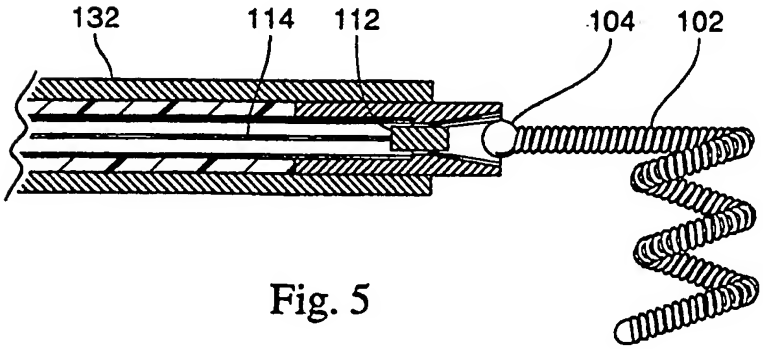

Fig. 5

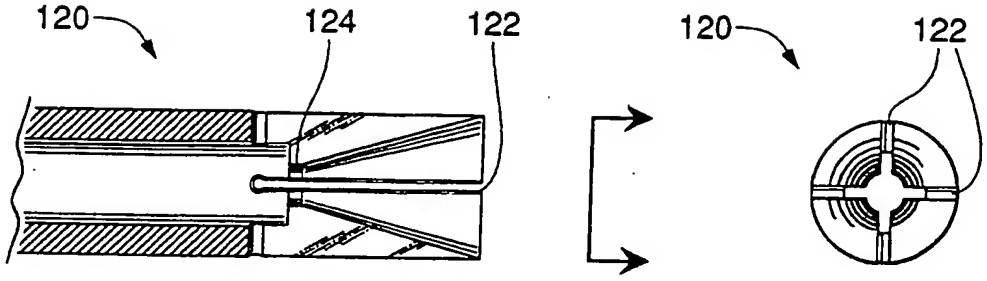

Fig. 2

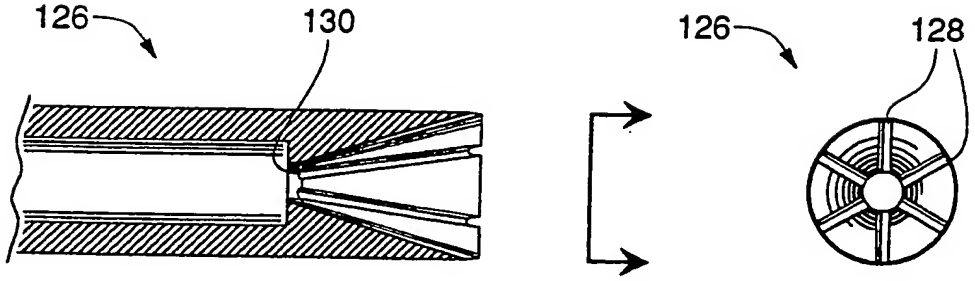

Fig. 3

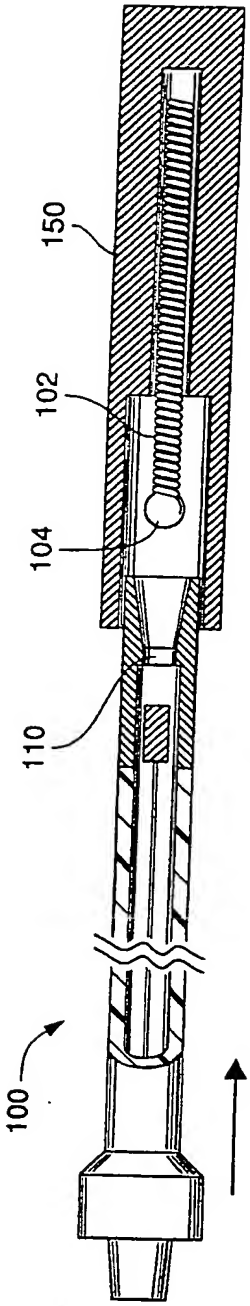

Fig. 6

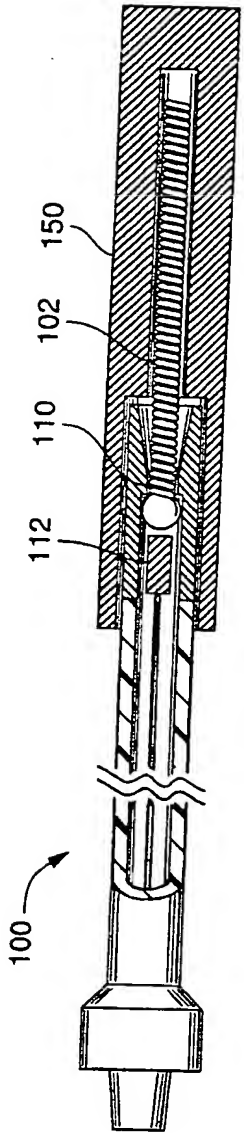

Fig. 7

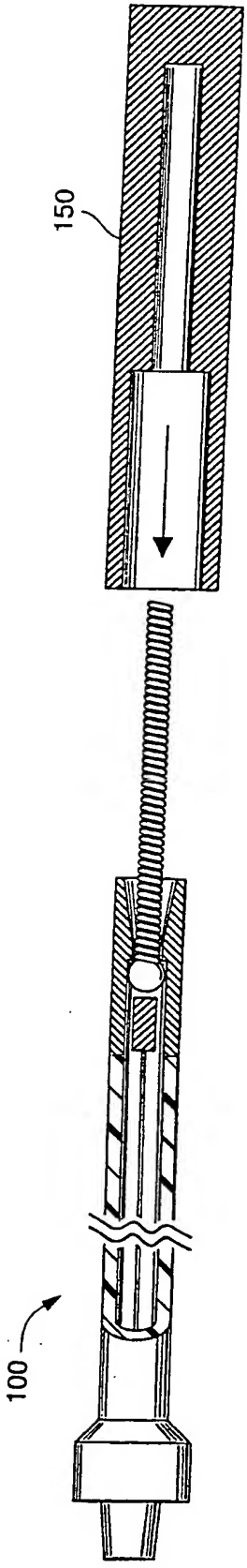

Fig. 8

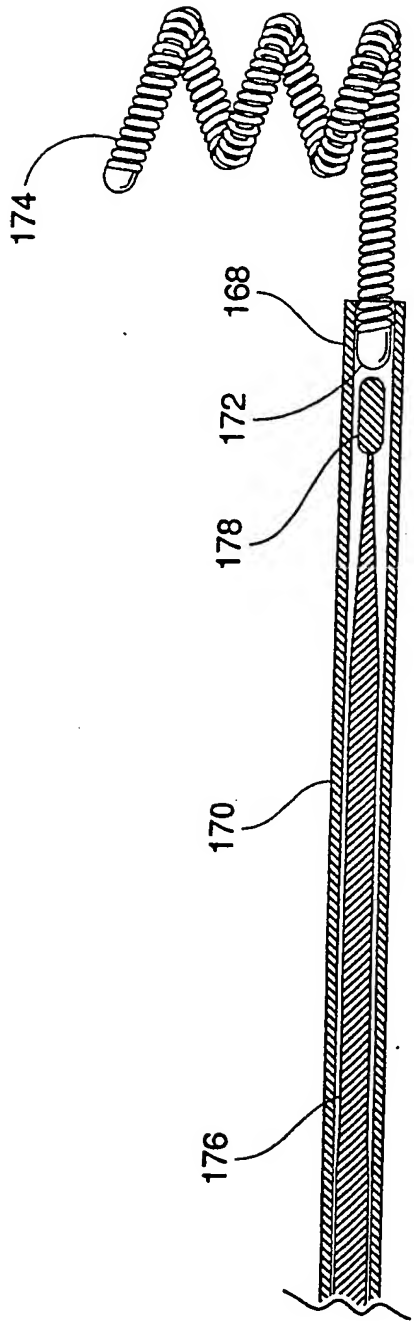

Fig. 9

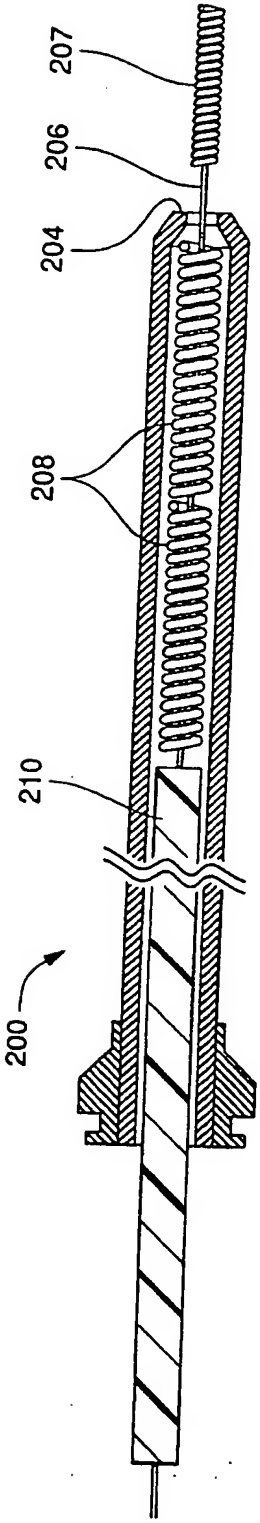

Fig. 10

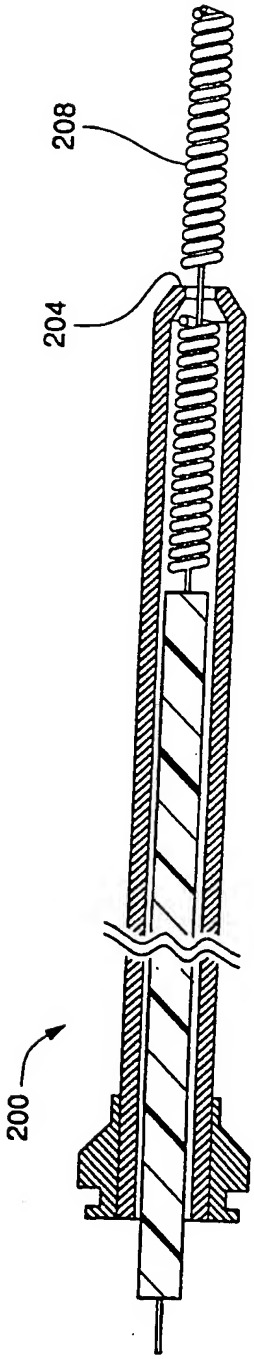

Fig. 11

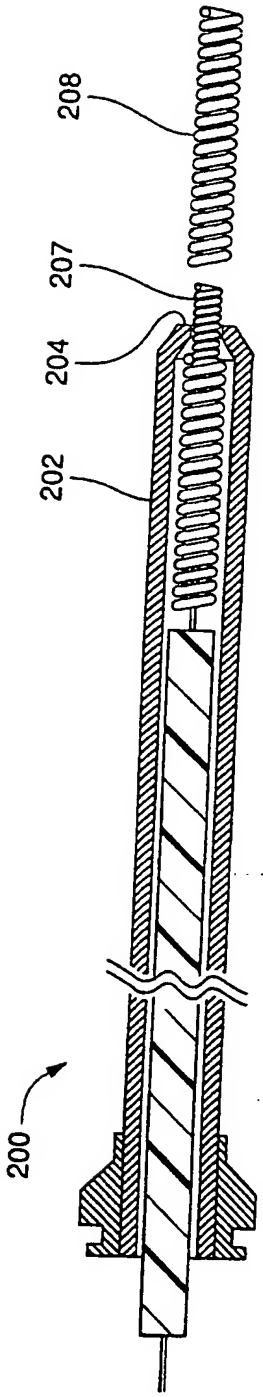

Fig. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/08346

A. CLASSIFICATION OF SUBJECT MATTER
IPC(5) :A61M 29/00
US CL :606/108, 191; 128/898
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/1, 108, 151, 159, 190, 191, 194, 195, 198, 200; 604/11-15, 159, 164; 623/1; 128/772, 898

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---, P Y	US, A, 5,217,484 (Marks) 08 June 1993. See Figs. 2 and 4.	1-5 ------- 6-13
X	US, A, 5,109,867, (Twyford, Sr), 05 May 1992. See Figs. 3 and 4.	1-5
Y	US, A, 4,512,338 (Balko et al) 23 April 1985. See column 4, lines 38-47.	6-13
X	US, A, 4,830,003 (Wolff et al.) 16 May 1989. See Figs. 7 and 8.	14, 20-23
X --- Y	US, A, 5,037,427 (Harada et al.) 06 August 1991.	16, 17 ---------- 15, 18, 19

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
14 December 1993

Date of mailing of the international search report
MAR 10 1994

Name and mailing address of the ISA/US
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Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/08346

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO, A, 91/17789 (Stack et al.) 28 November 1991.	1-23
A	US, A, 5,122,136 (Guglielmi et al) 16 June 1992.	1-23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/08346

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group I, claims 1-13, drawn to the product of Figs. 1-8 and the method of using the product.
Group II, claims 14-23, drawn to the product of Figs. 10-12.
The claims of these two groups are directed to different products which are not so linked as to form a single inventive concept. The claims are drawn to mutually exclusive characteristics of each of the two groups. There are currently no claims drawn to the product of Fig. 9.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims. (Telephone Practice)

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.